

- Reference:
- 1) Final Rule for Medical Device User Facility and Manufacturer Reporting, 21 CFR 803, effective July 31, 1996.
  - 2) MDR Reporting Guidance for Date-Related Problems Including Y2K issued on April 16, 1999.
  - 3) Remedial Action Exemption (RAE), E1996001, issued July 30, 1996.

Purpose: This document establishes a reporting exemption for firms that receive reports of MDR reportable malfunctions involving a Y2K related problem and decide not to initiate a remedial action.

The Center for Devices and Radiological Health (CDRH) has been exploring various means to identify and address anticipated date-related problems with medical devices, including problems that are related to the year 2000 (Y2K).

To assist industry and the clinical community with the interpretation of MDR reporting for date-related events, the guidance document “MDR Reporting Guidance For Date-Related Problems Including Y2K” was issued on April 16, 1999. Section IV of the MDR guidance document for date-related problems describes the Remedial Action Exemption (RAE) that is available. Section IV also indicated that FDA would issue an exemption for reportable malfunctions where no remedial action is taken to correct the malfunction. This document, E1999018, provides that exemption.

Pursuant to 21 CFR 803.19, MDR reportable malfunctions that are related to Y2K problems and that do not result in a remedial action as defined in 21 CFR 803.3(y), will not require the submission of individual malfunction event reports provided the manufacturer complies with the following conditions:

- (A) A "Y2K Exemption" notification is filed with FDA. This notification must be filed with, or after submission of, one or more 30-day initial MDR reports on a Y2K related event. The MDR reports must be filed within the required timeframes. A manufacturer cannot utilize this exemption until at least one applicable MDR report is filed. Any associated product baseline reports must also be filed with the 30-day report(s) in accordance with 21 CFR 803.55.
- (B) The Y2K notification must reference E1999018 and state that future incidents meeting all of the conditions in the exemption will not be submitted. The notification must include all of the following information:
  - (1) the range of device model numbers, catalog numbers, serial numbers, or lot numbers affected by the Y2K problem,
  - (2) a complete description of the reported problem, which adequately explains how the device(s) is affected by the Y2K problem,

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- (3) an explanation of the reasons the firm concluded that a remedial action is not needed to address the Y2K problem, and
  - (4) the manufacturer report number(s) as reported on the 30-day initial MDR report filed in association with the Y2K problem.
- (C) Any complaint involving the possible failure of a device to meet any of its specifications is reviewed, evaluated, and investigated as required by the Quality System Regulation, 21 CFR 820.198.
- (D) There is prompt verification that the event was caused solely by the same Y2K problem as addressed by the Y2K notification.
- (E) An event that is determined to have other problems in addition to the Y2K problem subject of a notification, does not qualify for exemption under that notification.
- (F) The firm must conduct an investigation and/or make a determination that the failure mode is identical to that identified in the Y2K notification. The results of this investigation, including failure analysis or other evidence to support this conclusion, should be documented in the firm's files and must be made available to FDA upon request.

Individual MDR reports on Y2K events involving products under the Y2K notification will continue to be required if the above conditions cannot be met. Once a firm has concluded that these conditions cannot be met, the FDA will consider that the firm is aware of information that reasonably suggests that one of its marketed devices has been involved in an MDR reportable event.

The FDA reserves the right to modify or revoke this Y2K Exemption in whole or in part. If the manufacturer has met the conditions specified above, any modification or revocation of this exemption will not be applied retroactively to reports eligible for exemption on or prior to the date of the revocation or modification.

Y2K Exemption notifications should be mailed to the following address in an envelope marked "Y2K Exemption":

Food and Drug Administration  
Center for Devices and Radiological Health  
Medical Device Reporting  
P.O. Box 3002  
Rockville, MD 20847-3002

Questions regarding this exemption should be directed to Victoria Schmid (301) 594-2735.